provided herewith. It is requested that an initialed copy of the Form 1449 be forwarded to the undersigned with the next communication from the PTO.

It is also noted that an initialed copy of the PTO Form 1449 that was submitted with Applicants' Information Disclosure Statement mailed January 31, 2002 has not been returned to Applicants' representative with the Office Action. Accordingly, it is requested that an initialed copy of the Form 1449 be forwarded to the undersigned with the next communication from the PTO. In order to facilitate review of the references by the Examiner, a copy of the Information Disclosure Statement, the Form 1449, and the return postcard indicating receipt by the OIPE on February 15, 2002 are attached hereto. A copy of the cited references was provided at the time of filling the original Information Disclosure Statement, and, therefore, an addition copy of the references is not submitted herewith. Applicants will be pleased to provide an additional copy of the reference upon the Examiner's request if it proves difficult to locate the original reference.

The Rejection Under 35 U.S.C. § 101 Should be Withdrawn

The Examiner has rejected claims 15 and 16 under 35 U.S.C. § 101 on the grounds that they are drawn to non-statutory subject matter because they encompass human organisms. Claims 15 and 16 have been amended as suggested by the Examiner, thereby obviating the rejection.

The Rejections Under 35 U.S.C. 112, First Paragraph, Should be Withdrawn

Claims 1-3, 7-8, 10-18, and 26-36 have been rejected on the grounds that they contain subject matter that was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is traversed for the reasons described below.

The Examiner argues that the specification of the instant application provides support for a receptor with *Bt* toxin binding but does not provide support for a polypeptide with Bt toxin binding activity. Applicants note that by definition, all *Bt* toxin receptors have *Bt* binding activity. Furthermore, literal support for the language in the claim is found in the specification.

See, for example, line 23 of page 3, lines 11-14 of page 17, and line 10 of page 18 of the specification. Nevertheless, in order to expedite prosecution, claims 1, 7, 26-29, and 32-35 have been amended to recite a receptor polypeptide having *Bt* toxin binding activity, thereby obviating the rejection.

The rejection of claims 1-3, 7, 8, 10-18, and 26-36 under 35 U.S.C. § 112, first paragraph, has been maintained on the grounds that these claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is traversed for the reasons described below.

The Examiner argues that there is not a sufficient written description of a nucleotide sequence encoding a polypeptide having *Bt* toxin binding activity, where the nucleotide sequence has at least a designated level of sequence identity to the nucleotide set forth in SEQ ID NO:1 or contains at least a designated number of contiguous nucleotides of SEQ ID NO:1 because the specification does not describe each critical amino acid required for receptor activity, and because the specification does not describe *Bt* toxin receptors that are not from the order *Lepidoptera*. Thus, in maintaining the rejection, the Examiner has continued to require that the Applicants disclose each sequence falling within the claimed genus. In the Amendment mailed May 10, 2002, the Applicants presented arguments demonstrating that the requirement imposed by the Examiner is inconsistent with the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, ¶ 1, 'Written Description' Requirement" (66 Fed. Reg. 1099 (2001)) or the supporting case law. Applicants note that the *Manual of Patent Examining Procedure (*MPEP*)* provides that "[w]here the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." MPEP § 707.07(f) (8th ed.). However, in the Office Action mailed October 18, 2002, the Examiner did not respond to the Applicants' arguments regarding the correct legal standard for written description of a genus of nucleic acid molecules. Therefore, these arguments are presented again below.

The "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement" state that genus may be described by "sufficient description of a representative number of species . . . or by disclosure of relevant, identifying characteristics , *i.e.* structure or other physical and/or chemical properties." *Id.* at 1106. This is in accordance with the standard for written description set forth in *Regents of the University of California v. Eli Lilly & Co*, 119 F.3d 1559 (Fed. Cir. 1997), where the court held that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, or chemical name' of the claimed subject matter sufficient to distinguish it from other materials." 119 F.3d at 1568, citing Fiers v. Revel 984 F.2d 1164 (Fed. Cir. 1993).

The structural limitations recited in claims 1-3, 16-18, 26-29, and 32-35 meet this requirement. The claims recite the identifying structural characteristics that define each genus of nucleotide sequences or amino acid sequences. Claims 1-3, 16-18, and 26-29, and 32 as amended recite nucleotide sequences having at least 65%, 70%, 75%, 85%, or 95% sequence identity with the nucleotide sequence set forth in SEQ ID NO:1, nucleotide sequences that hybridize to the full length complement of the nucleotide sequence set forth in SEQ ID NO:1 under stringent conditions, and nucleotide sequences consisting of at least 22 contiguous nucleotides of the nucleotide sequence set forth in SEQ ID NO:1. Claims 33-35 recite nucleotide sequences encoding a fusion polypeptide comprising at least one polypeptide of interest and a polypeptide having at least 75%, at least 85%, or at least 95% sequence identity with the amino acid sequence set forth in SEQ ID NO:2. These structural limitations are sufficient to distinguish the claimed nucleotide sequences from other materials and thus sufficiently define the claimed genus.

Furthermore, the court in *Lilly* held that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus ***or*** of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." 119 F.3d at 1569, *emphasis added.* The recitation of the structural features of sequence identity with SEQ

ID NO:1 or SEQ ID NO:2, hybridization with SEQ ID NO:1, or the presence of subsequences of SEQ ID NO:1 or SEQ ID NO:2 of a given minimum length is sufficient to satisfy this requirement.

Applicants have further provided the functional characteristics that distinguish the claimed sequences of the genus. Specifically, the claims recite that the receptor variants and fragments have *Bt* toxin binding activity. Accordingly, both the structural properties and the functional properties that characterize the claimed genus are specifically recited in the claims.

Applicants note that the standard for written description set forth in the Office Action is at odds with the "Revised Interim Written Description Guidelines Training Materials" available at www.uspto.gov/web/menu/written.pdf. Example 14 of the "Training Materials" provides a written description assessment for a claim to a protein having at least 95% sequence identity to the sequence of SEQ ID NO:3, wherein the sequence catalyzes the reaction A → B. The conclusion in the Training Materials is that the generic claim of Example 14 is sufficiently described under §112, first paragraph, because 1) "the single sequence disclosed in SEQ ID NO:3 is representative of the genus" and 2) the claim recites a limitation requiring the compound to catalyze the reaction from A → B, and therefore one of skill in art would recognize that the Applicants were in possession of the necessary common attributes possessed by the members of the genus.

Following the analysis of Example 14, Applicants submit that claims 1-3, 16-18, 26-29 and 32-35 satisfy the written description requirements of § 112, first paragraph. Specifically, the claims of the present invention encompass nucleotide sequences having sequence identity to the nucleotide sequence of SEQ ID NO:1, hybridizing under stringent conditions to the full length complement of the nucleotide sequence of SEQ ID NO:1, comprising a subsequence of SEQ ID NO:1, or encoding a polypeptide having sequence identity with SEQ ID NO:2, wherein the claimed sequences encode a polypeptide having a specified activity. As in Example 14, the specification discloses the nucleic acid sequence of SEQ ID NO:1, and the claims recite a limitation requiring the compound to have a specific function (*i.e.*, *Bt* toxin binding activity). Accordingly, claims 1-3, 16-18, 26-29, and 32-35 provide the relevant, identifying characteristics

that describe the claimed genus, and one of skill in the art would recognize that the inventors were in possession of the claimed invention.

The Examiner argues that structural features have not been provided for the claimed genera of sequences because claims encompass "fragments of SEQ ID NO:1 where no open reading frame exists or encompasses unknown and undescribed heterologous amino acid sequences fused to fragments, in general, where the critical amino acids for Bt toxin activity are not recited, and otherwise, are unknown." October 18, 2002 Office Action, page 4. With respect to the Examiner's statements regarding fragments of SEQ ID NO:1, Applicants note that the recitation that the claimed fragments consist of at least 22 contiguous nucleotides of the nucleotide sequence set forth in SEQ ID NO:1 provides the structural feature that is shared by and characterizes all members of the genus. This structural feature is sufficient to distinguish the members of the claimed genus of sequences from other sequences. Accordingly, this limitation satisfies the standard for written description set forth in *Lilly*. Furthermore, the claimed genus of nucleotide sequences contains the additional limitation that it encode a receptor polypeptide having *Bt* toxin binding activity. Thus, contrary to the statement in the office action, fragments with no open reading frame are not encompassed by the claims. Finally, the Examiner's requirement that every residue essential to *Bt* toxin binding activity be disclosed in order to satisfy the written description requirement is not supported by the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, ¶ 1, 'Written Description' Requirement" or the supporting case law for the reasons described above.

The Examiner cites page 18 of the specification for the statement "it is difficult to predict the exact effect of the substitution, deletion, or insertion in advance of doing so." In fact, the Examiner has quoted only part of the sentence in which this phrase is found, thereby substantially altering the phrase's meaning. Lines 28-30 of page 18 specification actually state, "[h]owever, when it is difficult to predict the exact effect of the substitution, deletion, or insertion in advance of doing so, one skilled in the art will appreciate that the effect will be evaluated by routine screening assays." Accordingly, the statement in the specification demonstrates that methods of identifying functional variants and fragments of a *Bt* receptor are

routinely performed, and that the specification reasonably conveys to one of skill in the art that the Applicants were in possession of the claimed genera of nucleic acid molecules at the time the application was filed.

In the Office Action mailed October 18, 2002, the Examiner suggests that the claims be amended to recite a "*Lepidopteran*" insect receptor. Claims 1, 7, 26-29 and 32-35 have been amended as suggested by the Examiner in order to clarify that the polypeptides recited in the claims have *Lepidopteran* insect receptor activity. Support for the amendment may be found on lines 21-22 on page 3 of the specification.

Claims 1-3, 7-8, 10-18, and 32 have been rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not provide enablement for fragments of SEQ ID NO:1 and SEQ ID NO:2. The rejection is traversed for the reasons described below.

The Examiner states that "[i]n contrast to Applicants' assertion on pages 9-11 of the response, a fragment that does not consist of at least the extracellular part of this receptor would not reasonably bind Bt toxin ." October 18, 2002 Office Action, page 6. Contrary to the Examiner's assertions, Applicants have not argued that fragments of the receptor that do not contain the extracellular part of the receptor would have *Bt* toxin binding activity. Rather, Applicants have argued that the specification provides a rational scheme for determining the regions of the *Bt* toxin receptor that would tolerate modification. Thus, the specification provides sufficient guidance to allow one of skill in the art to make and use the invention, thereby satisfying the requirement for an enabling disclosure.

The Examiner argues that because every fragment that meets the structural limitation of the claims will not also meet the functional limitation of the claims, the specification is not enabling. The standard for enablement set forth in the Office Action is not supported by the applicable case law. Applicants note that an enabling disclosure must describe the claimed invention in such a way as to enable the ordinarily skilled artisan to make and use the invention, and that this description be commensurate with the scope of the claimed invention. The test of enablement is not whether experimentation is necessary, but rather if experimentation *is*

necessary, whether it is undue. *In re Angstadt*, 198 USPQ 214, 219 (C.C.P.A. 1976). The test of whether an invention requires undue experimentation is not based on a single factor, but rather is a conclusion reached by weighing many factors. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Factors to be considered in determining whether undue experimentation is required include the quantity of experimentation necessary, the amount of guidance provided in the specification, the presence of working examples of the invention in the application, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability in the art, and the breadth of the claimed invention. *Id.* at 1404. Accordingly, the holding of *Wands* does not require that an applicant identify every functional fragment of the disclosed sequences so that no experimentation is required to make and use these fragments as argued by the Examiner. Rather, the court in *Wands* set forth factors to be considered in determining whether undue experimentation is required to make and use the claimed invention.

As described on pages 9 and 10 of the Amendment mailed May 10, 2002, Applicants have provided guidance for determining the regions of the *Bt* toxin receptor that would tolerate modification. Based on the working examples of *Bt* toxin receptors provided in the specification and the guidance provided on page 35 of the specification regarding the presence of *Bt* toxin functional motifs, a skilled artisan could choose among possible modifications to produce polypeptides within the structural parameters set forth in the claims and test these modified variants to determine if they retain *Bt* toxin binding activity. Making and testing such variants is routine to those of skill in the art.

Accordingly, when all of the factors set forth in *Wands* are considered together, it is clear that although some quantity of experimentation would be required to produce functional *Bt* toxin receptors, the level of experimentation would not be undue in view of the nature of the invention, the state of the prior art (where *Bt* toxin receptor functional domains and activities have been described), the relative skill of those in the art (to whom the making and testing of variants is routine), the predictability in the art, the amount of direction provided in the specification (which provides guidance regarding preferred types of amino acid substitutions and describes assays for identifying functional *Bt* toxin receptors), the breadth of the claimed invention (for which the

scope is defined by both structural and functional limitations), and the existence of several working examples of functional *Bt* toxin receptors. These factors support the conclusion that one of skill in the art could practice the claimed invention without undue experimentation.

The Examiner cites Rudinger in *Peptide Hormones*, J.A. Parsons Ed. University Park Press, Baltimore, June 1976 in support of the rejection for lack of enablement, and quotes from page 6 of Rudinger, which states, "[t]he significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study." While the statements made by Rudinger regarding the correlation between amino acid sequence and polypeptide function may accurately reflect the views of those of skill in the art at the time of publication of this reference (*i.e.*, **1976**), this statement is not an accurate representation the view of those of skill in the art at the time the priority document for the present application was filed (*i.e.*, **1999**). The cited reference predates essentially the entire field of modern molecular biology. For example, the first recombinant bacterial plasmids were reported in the literature in 1973, only three years prior to the publication date of Rudinger. *See*, Cohen *et al.* (1973) *Proc. Natl. Acad. Sci. USA* 70:3240-4. Efficient methods for sequencing nucleotide sequences were not described until 1977, one year after the publication date of the Rudinger reference. *See*, Maxam *et al.* (1977) *Proc. Natl. Acad. Sci. USA* 74:560-564). Accordingly, while making and testing protein variants may have required painstaking experimental study at the time that the Rudinger reference was published, this reference does not accurately reflect the state of the art for identifying functional protein variants in 1999 when the priority document for the present application was filed.

In view of the above arguments, all grounds for rejection under 35 U.S.C. § 112, first paragraph for insufficient written description and lack of enabling disclosure have been overcome. Reconsideration and withdrawal of the rejections are therefore respectfully requested.

The Rejection Under 35 U.S.C. § 112, Second Paragraph Should be Withdrawn

Claims 1-3 have been rejected on the grounds that they are indefinite under 35 U.S.C. § 112, second paragraph, on the grounds that only a sequence that hybridizes to the complement of SEQ ID NO:1 will encode a functional receptor. Claim 1 has been amended to recite a nucleotide sequence that hybridizes under stringent conditions to the full-length complement of the nucleotide sequence of a), thereby obviating the rejection.

Claims 1-3, 7-8, 10-18, 26-29, and 33-35 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting the term "about." Claims 1-3, 7-8, 10-18, 26-29, and 33-35 have been amended to delete this term, thereby obviating the rejection.

In view of the above amendments, all grounds for rejection under 35 U.S.C. § 112, second paragraph have been overcome. Reconsideration and withdrawal of the rejection are respectfully requested.

The Rejection Under 35 U.S.C. § 102(b) Should be Withdrawn

Claims 1-3, 7-8, and 10-16 have been rejected under 35 U.S.C. § 102(b) on the grounds that they are anticipated by U.S. Patent No. 5,693,491. It is respectfully submitted that the rejection should not be applied to these claims as amended.

U.S. Patent No. 5,693,491 teaches a Bt toxin receptor from *M. Sexta* that has approximately 60% sequence identity with SEQ ID NO:2 and is 100% identical with residues 1023-1038 of SEQ ID NO:2. The nucleotide sequence encoding the receptor shares short regions of identity with SEQ ID NO:1.

Clause b) of claim 1 has been amended to recite a nucleotide sequence having at least 65% sequence identity to the nucleotide sequence of clause a). Support for the amendment may be found on line 2 of page 17 of the specification. Clause h) of claim 1 has been amended to recite a nucleotide sequence that hybridizes under stringent conditions to the full-length complement of the nucleotide sequence of clause a). Original clause b) of claim 7 has been

deleted, and the new clause b) recites a nucleotide sequence having at least 65% sequence identity to the amino acid sequence set forth in SEQ ID NO:2. Support for this amendment maybe be found on line 16 of page 17 of the specification. Clause h) of claim 7 has been amended to recite a polypeptide consisting of at least 25 contiguous residues of the amino acid sequence set forth in SEQ ID NO:2. Support for this amendment may be found on page 16, line 5 of the specification. Accordingly, claims 1 and 7 as amended and their respective dependent claims are not anticipated by U.S. Patent Number 5,693,491.

In view of the above amendments, all grounds for rejection under 35 U.S.C. § 102 have been overcome. Reconsideration and withdrawal of the rejections are respectfully requested.

CONCLUSION

It is believed that all the rejections have been obviated or overcome and the claims are in conditions for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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Nora C. Martinez

Nora C. Martinez

Version with Markings to Show Changes Made:

In the Claims:

Please amend claims 1, 7, 15, 16, 26-29, and 32-35 as follows.

1. (Twice amended) An isolated nucleic acid molecule having a nucleotide sequence encoding a *Lepidopteran* insect receptor polypeptide having *Bt* toxin binding activity, wherein said nucleotide sequence is selected from the group consisting of:

a) the nucleotide sequence set forth in SEQ ID NO: 1;

b) a nucleotide sequence having at least 65%[about 60 %] identity to the nucleotide sequence of a);

c) a nucleotide sequence having at least [about]70 % identity to the nucleotide sequence of a);

d) a nucleotide sequence having at least [about]75 % identity to the nucleotide sequence of a);

e) a nucleotide sequence having at least [about]85 % identity to the nucleotide sequence of a);

f) a nucleotide sequence having at least [about]95 % identity to the nucleotide sequence of a);

g) a nucleotide sequence consisting of at least 22 contiguous nucleotides of the nucleotide sequence set forth in SEQ ID NO:1;

h) a nucleotide sequence that hybridizes under stringent conditions to the full length complement of the nucleotide sequence of a), said stringent conditions comprising hybridization in 50% formamide, 1 M NaCl, 1% SDS at 37°C, followed by a wash in 0.1X SSC at 60 to 65°C; and

i) a nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO:2.

7. (Twice amended) An expression cassette comprising a nucleotide sequence encoding a fusion polypeptide comprising at least one polypeptide of interest and a polypeptide selected from the group consisting of:

a) a polypeptide having the amino acid sequence set forth in SEQ ID NO:2;

[b) a polypeptide having at least about 52% sequence identity to the amino acid sequence set forth in SEQ ID NO: 2, wherein said polypeptide has *Bt* toxin binding activity;]

b)[c)] a *Lepidopteran* insect receptor polypeptide having at least 65%[about 60%] sequence identity to the amino acid sequence set forth in SEQ ID NO:2, wherein said polypeptide has *Bt* toxin binding activity;

c)[d)] a *Lepidopteran* insect receptor polypeptide having at least [about]70% sequence identity to the amino acid sequence set forth in SEQ ID NO:2, wherein said polypeptide has *Bt* toxin binding activity;

d)[e)] a *Lepidopteran* insect receptor polypeptide having at least [about]75% sequence identity to the amino acid sequence set forth in SEQ ID NO:2, wherein said polypeptide has *Bt* toxin binding activity;

e)[f)] a *Lepidopteran* insect receptor polypeptide having at least [about]85% sequence identity to the amino acid sequence set forth in SEQ ID NO:2, wherein said polypeptide has *Bt* toxin binding activity;

f)[g)] a *Lepidopteran* insect receptor polypeptide having at least [about]95% sequence identity to the amino acid sequence set forth in SEQ ID NO:2, wherein said polypeptide has *Bt* toxin binding activity;

g)[h)] a *Lepidopteran* insect receptor polypeptide consisting of at least 25[about 15] contiguous residues of the amino acid sequence set forth in SEQ ID NO:2, wherein said polypeptide has *Bt* toxin binding activity; and

h)[i)] a polypeptide encoding a nucleotide sequence according to claim 1;

wherein said nucleotide sequence encoding the fusion polypeptide is operably linked to a promoter capable of initiating the transcription of the nucleotide sequence.

15. (Amended) An isolated[A] cell containing the vector of claim 14.

16. (Twice amended) An isolated[A] transformed cell having stably incorporated within its genome a nucleotide sequence according to claim 1.

26. (Amended) The isolated nucleic acid molecule of claim 1 wherein said nucleotide sequence encoding a *Lepidopteran* insect receptor polypeptide having *Bt* toxin binding activity is a nucleotide sequence having at least [about]70 % identity to the nucleotide sequence set forth in SEQ ID NO:1.

27. (Amended) The isolated nucleic acid molecule of claim 1 wherein said nucleotide sequence encoding a *Lepidopteran* insect receptor polypeptide having *Bt* toxin binding activity is a nucleotide sequence having at least [about]75 % identity to the nucleotide sequence set forth in SEQ ID NO:1.

28. (Amended) The isolated nucleic acid molecule of claim 1 wherein said nucleotide sequence encoding a *Lepidopteran* insect receptor polypeptide having *Bt* toxin binding activity is a nucleotide sequence having at least [about]85 % identity to the nucleotide sequence set forth in SEQ ID NO:1.

29. (Amended) The isolated nucleic acid molecule of claim 1 wherein said nucleotide sequence encoding a *Lepidopteran* insect receptor polypeptide having *Bt* toxin binding activity is a nucleotide sequence having at least about 95 % identity to the nucleotide sequence set forth in SEQ ID NO:1.

32. (Amended) The isolated nucleic acid molecule of claim 1 wherein said nucleotide sequence encoding a *Lepidopteran* insect receptor polypeptide having *Bt* toxin binding activity

comprises a nucleotide sequence consisting of at least 22 contiguous nucleotides of the nucleotide sequence set forth in SEQ ID NO:1.

33. (Amended) The expression cassette of claim 7, wherein said expression cassette comprises a nucleotide sequence encoding a fusion polypeptide comprising at least one polypeptide of interest and a *Lepidopteran* insect receptor polypeptide having at least[about] 75% sequence identity to the amino acid sequence set forth in SEQ ID NO:2, wherein said *Lepidopteran* insect receptor polypeptide having at least [about]75% sequence identity to the amino acid sequence set forth in SEQ ID NO:2 has *Bt* toxin binding activity.

34. (Amended) The expression cassette of claim 33, wherein said expression cassette comprises a nucleotide sequence encoding a fusion polypeptide comprising at least one polypeptide of interest and a *Lepidopteran* insect receptor polypeptide having at least[about] 85% sequence identity to the amino acid sequence set forth in SEQ ID NO:2, wherein said *Lepidopteran* insect receptor polypeptide having at least[about] 85% sequence identity to the amino acid sequence set forth in SEQ ID NO:2 has *Bt* toxin binding activity.

35. (Amended) The expression cassette of claim 34, wherein said expression cassette comprises a nucleotide sequence encoding a fusion polypeptide comprising at least one polypeptide of interest and a *Lepidopteran* insect receptor polypeptide having at least[about] 95% sequence identity to the amino acid sequence set forth in SEQ ID NO:2, wherein said *Lepidopteran* insect receptor polypeptide having at least[about] 95% sequence identity to the amino acid sequence set forth in SEQ ID NO:2 has *Bt* toxin binding activity.